DETAILED ACTION

This application is the national stage entry of PCT/JP05/04152, filed 03 Mar 2005; and claims benefit of foreign priority document JAPAN 2004-61429, filed 04 Mar 2004.

Claims 1-20 and 25-29 are pending in the current application.

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a fused heterocyclic derivative and pharmaceutical compositions thereof.

Group II, claim(s) 17-20, drawn to a method comprising administering said fused heterocyclic derivative.

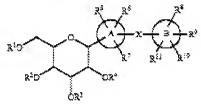
Group III, claim(s) 25 and 26, drawn to a pharmaceutical composition comprising said fused heterocyclic derivative in combination with at least one drug.

Group IV, claim(s) 27-29, drawn to a method comprising administering said fused heterocyclic derivative in combination with at least one drug.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
The common feature of the invention of Groups I-IV is a fused heterocyclic derivative. However, such a compound of is known product. See Imamura et al. (WIPO Publication WO2004/080990, published 23 Sep 2004, cited in PTO-892; US Patent 7,202,350, cited in PTO-892, is provided as an English-language equivalent), formula (I) of column 3 lines 45-58:

[1] C-glycoside derivatives of the following formula (I) and salts thereof:

[Chemical Formula]



wherein

the definition of hetercyclic ring A includes an unsaturated eight- to ten-membered bicycle hetero ring (column 3, lines 61-63), with specific example of benzimidazole provided (column 6, lines 2-3),

the definition of X includes lower alkylene (column 4, line 4), with specific example of methylene (column 6, line 27), and

the definition of ring B specifically includes a benzene ring (column 4, line 3).

This C-glycoside derivative as specifically disclosed by Imamura et al. is a fused heterocyclic derivative according to formula (I) of instant claim 1. Therefore said fused heterocyclic derivative is not the special technical feature of a single general inventive concept. The special technical feature of the invention of Group I is the specific chemical structure of a fused heterocyclic derivative and the specific disease or condition which said fused heterocyclic derivative treats. The special technical feature of the invention of Group II is the specific method of treatment of a specific disease or condition comprising administering a fused heterocyclic derivative having a specific chemical structure. The special technical feature of the invention of Group III is the specific combination of a fused heterocyclic derivative having a specific chemical structure and at least one specific drug. The special technical feature of the invention of Group II is the specific method of treatment of a specific disease or condition comprising administering a specific combination of a fused heterocyclic derivative having a specific chemical structure and at least one specific drug.

Election of Species Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

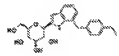
If Applicant restricts to the invention of Group I or II Applicant is required to make elections from both the following **first** and **second** species elections as a starting point to begin the search and examination process.

If Applicant restricts to the invention of Group III or IV Applicant is required to make elections from all of the following **first**, **second**, and **third** species elections as a starting point to begin the search and examination process.

First species election:

The species of fused heterocyclic derivative are as follows:

A fused heterocyclic derivative with a specific chemical structure, for example the



compound of Example 4, , disclosed in table 1 on page 101 of the specification.

Second species election:

The species of disease or condition treated by the method (disclosed in instant claims 17 and 19) or for which the compound is an agent for treatment (disclosed in instant claims 11 and 13) are as follows:

A specific disease or condition, for example diabetes disclosed in instant claims 13 and 19.

Third species election:

The species of drug in combination with said fused heterocyclic derivative as part of a pharmaceutical composition (disclosed in instant claims 25 and 26) or administered as part of a method of treatment (disclosed in instant claims 27-29) are as follows:

A specific drug or drugs as disclosed in the specification on pages 69-83, for example the insulin sensitivity enhancer troglitazone, disclosed on page 69, line 19 of the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

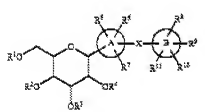
The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-20 and 25-29 are generic to the species of fused heterocyclic derivative and the species of disease or condition treated by the method or for which the compound is an agent for treatment.
Claims 25-29 are generic to the species of drug in combination with said fused heterocyclic derivative.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:
The common feature of the invention of Groups I-IV is a fused heterocyclic derivative. However, such a compound of is known product. See Imamura et al. (WIPO Publication WO2004/080990, published 23 Sep 2004, cited in PTO-892; US Patent 7,202,350, cited in PTO-892, is provided as an English-language equivalent), formula (I) of column 3 lines 45-58:

[1] C-glycoside derivatives of the following formula (I) and salts thereof:

[Chemical Formula] 45



(I) 50

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wherein

the definition of hetercyclic ring A includes an unsaturated eight- to ten-membered bicycle hetero ring (column 3, lines 61-63), with specific example of benzimidazole provided (column 6, lines 2-3),

the definition of X includes lower alkylene (column 4, line 4), with specific example of methylene (column 6, line 27), and

the definition of ring B specifically includes a benzene ring (column 4, line 3).

This C-glycoside derivative as specifically disclosed by Imamura et al. is a fused heterocyclic derivative according to formula (I) of instant claim 1. Therefore said fused heterocyclic derivative is not the special technical feature of a single general inventive concept. The special technical feature of the invention of Group I is the specific chemical structure of a fused heterocyclic derivative and the specific disease or condition which said fused heterocyclic derivative treats. The special technical feature of the invention of Group II is the specific method of treatment of a specific disease or condition comprising administering a fused heterocyclic derivative having a specific chemical structure. The special technical feature of the invention of Group III is the specific combination of a fused heterocyclic derivative having a specific chemical structure and at least one specific drug. The special technical feature of the invention of Group II is the specific method of treatment of a specific disease or condition comprising administering a specific combination of a fused heterocyclic derivative having a specific chemical structure and at least one specific drug.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is (571)270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL

/Ardin H Marschel/
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